IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HORIZON PHARMA, INC. and HORIZON PHARMA USA, INC., *Plaintiffs,* v. ALKEM LABORATORIES LTD., *Defendant.*	C.A. No. _____

COMPLAINT

Plaintiffs Horizon Pharma, Inc. and Horizon Pharma USA, Inc. (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendant Alkem Laboratories Ltd. ("Defendant" or "Alkem"), and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, arising from Defendants' filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Plaintiffs' pharmaceutical product DUEXIS® (Ibuprofen and Famotidine Tablets) 800 mg/26.6 mg ("DUEXIS®") prior to the expiration of United States Patent Nos. 8,067,033 ("the '033 patent"), 8,067,451 ("the '451 patent"), 8,309,127 ("the '127 patent"), 8,318,202 ("the '202 patent"), 8,449,910 ("the '910 patent"), and 8,501,228 ("the '228 patent"), which cover DUEXIS® and its use.

THE PARTIES

2. Plaintiff Horizon Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 150 S. Saunders Rd, Lake Forest, Illinois.

3. Plaintiff Horizon Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 150 S. Saunders Rd, Lake Forest, Illinois.

4. On information and belief, Defendant Alkem Laboratories Ltd. is a corporation operating an existing under the laws of India, having a principal place of business at Devashish Building, Alkem House, Senapti Bapat Road, Lower Parel, Mumbai, 400 013.

5. On information and belief, Alkem is in the business of, inter alia, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this judicial district, through its own actions.

6. On information and belief, Defendant participated in the research and development, and the preparation and filing, of ANDA No. 211890 ("the Alkem ANDA") for ibuprofen and famotidine tablets ("the Alkem Product"), continues to seek FDA approval of that application, and intends to commercially manufacture, market, offer for sale and sell the Alkem Product throughout the United States, including in the State of Delaware, in the event the FDA approves Alkem's ANDA.

7. On information and belief, should the Alkem ANDA be finally approved by FDA, Alkem will sell, offer for sale, and distribute the Alkem Product throughout the United States, including within this judicial district.

8. On information and belief, Alkem has admitted to, consented to or has not contested, the jurisdiction of this Court in at least sixteen prior District of Delaware actions: *H. Lundbeck A/S et al. v. Alkem Labs. Ltd.*, Civil Action No. 1:18-cv-00089; *Takeda Pharmaceuticals U.S.A., Inc. v. Alkem Labs. Ltd.*, Civil Action No. 1:18-cv-00189; *Bial-Portela & CA S.A. et al. v. Alkem Labs. Ltd. et al.*, Civil Action No. 1:18-cv-00304; *Medicis Pharmaceutical Corp. v. Alkem Labs. Ltd.*, Civil Action No. 1:12-cv-01663; *Pfizer Inc. et al. v. Alkem Labs. Ltd. et al.*, Civil Action No. 1:13-cv-01110; *Sanofi et al. v. Alkem Labs. Ltd. et al.*, Civil Action No. 1:14-cv-00264; *Sanofi et al. v. Alkem Labs Ltd.*, Civil Action No. 1:14-cv-00292; *Accorda Therapeutics Inc. et al. v. Alkem Labs. Ltd. et al.*, Civil Action No. 1:14-cv-00882; *Accorda Therapeutics Inc. et al. v. Alkem Labs. Ltd.*, Civil Action No. 1:14-00917; *Sanofi et al. v. Alkem Labs. Ltd. et al.*, Civil Action No. 1:15-cv-00415; *Sanofi et al. v. Alkem Labs. Ltd.*, Civil Action No. 1:15-cv-01200; *Shire Development LLC et al. v. Alkem Labs. Ltd.*, Civil Action No. 1:16-00747; *Amgen Inc. v. Alkem Labs. Ltd.*, Civil Action No. 1:17-cv-00815; *Biogen Int'l GmbH et al. v. Alkem Labs. Ltd. et al.*, Civil Action No. 1:17-cv-00850; *Insys Therapeutics, Inc. et al. v. Alkem Labs. Ltd. et al.*, Civil Action No. 1:17-cv-01419; *Biogen Int'l GmbH et al. v. Alkem Labs. Ltd. et al.*, Civil Action No. 1:17-cv-00823.

9. On information and belief, Alkem has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least ten prior District of Delaware actions: *H. Lundbeck A/S et al. v. Alkem Labs. Ltd.*, Civil Action No. 1:18-cv-00089; *Bial-Portela & CA S.A. et al. v. Alkem Labs. Ltd. et al.*, Civil Action No. 1:18-cv-00304; *Medicis Pharmaceutical Corp. v. Alkem Labs. Ltd.*, Civil Action No. 1:12-cv-01663; *Pfizer Inc. et al. v. Alkem Labs. Ltd. et al.*, Civil Action No. 1:13-cv-01110; *Sanofi et al. v. Alkem Labs Ltd.*, Civil Action No. 1:14-cv-00292; *Accorda Therapeutics Inc. et al. v. Alkem Labs. Ltd.*, Civil Action

No. 1:14-00917; *Shire Development LLC et al. v. Alkem Labs. Ltd.*, Civil Action No. 1:16-00747; *Amgen Inc. v. Alkem Labs. Ltd.*, Civil Action No. 1:17-cv-00815; *Biogen Int'l GmbH et al. v. Alkem Labs. Ltd. et al.*, Civil Action No. 1:17-cv-00850; *Insys Therapeutics, Inc. et al. v. Alkem Labs. Ltd. et al.*, Civil Action No. 1:17-cv-01419.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

11. This Court has personal jurisdiction over Defendant by virtue of, *inter alia*, its presence in Delaware, having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law such that it should reasonably anticipate being haled into court in this judicial district, previously submitting to personal jurisdiction in this Court, availing itself of the jurisdiction of this Court (*e.g.*, by assertion of claims and counterclaims), and having engaged in systematic and continuous contacts with the State of Delaware through the marketing and sales of generic drugs throughout the United States, and in particular within this judicial district, through the receipt of revenue from the sales and marketing of generic drugs products, including Alkem products, within this judicial district, and through its intent to market and sell the Alkem Product, if approved, to residents of this judicial district.

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PATENTS-IN-SUIT

13. On November 29, 2011, the U.S. Patent and Trademark Office ("USPTO") duly and legally issued the '033 patent entitled "Stable Compositions of Famotidine and Ibuprofen."

14. Horizon Pharma USA, Inc. is the sole assignee and owner of all right, title and interest in and to the ’033 patent, which discloses and claims, *inter alia*, methods for manufacturing tablets containing ibuprofen and famotidine for the treatment of ibuprofen-responsive ailments while reducing the risk of developing gastro-intestinal problems, such as ulcers. A true and correct copy of the ’033 patent is attached hereto as Exhibit A.

15. On November 29, 2011, the USPTO duly and legally issued the ’451 patent entitled “Methods and Medicaments for Administration of Ibuprofen.”

16. Horizon Pharma USA, Inc. is the sole assignee and owner of all right, title and interest in and to the ’451 patent, which discloses and claims, *inter alia*, methods for manufacturing tablets containing ibuprofen and famotidine for the treatment of ibuprofen-responsive ailments while reducing the risk of developing gastro-intestinal problems, such as ulcers. A true and correct copy of the ’451 patent is attached hereto as Exhibit B.

17. On November 13, 2012, the USPTO duly and legally issued the ’127 patent entitled “Stable Compositions of Famotidine and Ibuprofen.”

18. Horizon Pharma USA, Inc. is the sole assignee and owner of all right, title and interest in and to the ’127 patent, which discloses and claims, inter alia, methods for manufacturing tablets containing ibuprofen and famotidine for the treatment of ibuprofen-responsive ailments while reducing the risk of developing gastro-intestinal problems, such as ulcers. A true and correct copy of the ’127 patent is attached hereto as Exhibit C.

19. On November 27, 2012, the USPTO duly and legally issued the ’202 patent entitled “Stable Compositions of Famotidine and Ibuprofen.”

20. Horizon Pharma USA, Inc. is the sole assignee and owner of all right, title and interest in and to the ’202 patent, which discloses and claims, *inter alia*, methods for

manufacturing tablets containing ibuprofen and famotidine for the treatment of ibuprofen-responsive ailments while reducing the risk of developing gastro-intestinal problems, such as ulcers. A true and correct copy of the '202 patent is attached hereto as Exhibit D.

21. On May 28, 2013, the USPTO duly and legally issued the '910 patent entitled "Stable Compositions of Famotidine and Ibuprofen."

22. Horizon Pharma USA, Inc. is the sole assignee and owner of all right, title and interest in and to the '910 patent, which discloses and claims, *inter alia*, methods for manufacturing tablets containing ibuprofen and famotidine for the treatment of ibuprofen-responsive ailments while reducing the risk of developing gastro-intestinal problems, such as ulcers. A true and correct copy of the '910 patent is attached hereto as Exhibit E.

23. On August 6, 2013, the USPTO duly and legally issued the '228 patent entitled "Stable Compositions of Famotidine and Ibuprofen."

24. Horizon Pharma USA, Inc. is the sole assignee and owner of all right, title and interest in and to the '228 patent, which discloses and claims, *inter alia*, methods for manufacturing tablets containing ibuprofen and famotidine for the treatment of ibuprofen-responsive ailments while reducing the risk of developing gastro-intestinal problems, such as ulcers. A true and correct copy of the '228 patent is attached hereto as Exhibit F.

DUEXIS®

25. Horizon Pharma, Inc. is the owner of FDA-approved New Drug Application No. 025519 ("the DUEXIS® NDA") for ibuprofen and famotidine tablets (DUEXIS®), which is sold in the U.S. under the trade name DUEXIS®, and which is sold by Horizon Pharma USA, Inc.

26. The DUEXIS® tablet is currently approved by the FDA for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper

gastrointestinal ulcers, which in the clinical trials was defined as gastric and/or duodenal ulcer, in patients who are taking ibuprofen for those indications.

27. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the ’033, ’451, ’127, ’202, ’910 and ’228 patents are currently listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations (“the Orange Book”) for the DUEXIS® NDA.

28. The ’033, ’451, ’127, ’202, ’910 and ’228 patents cover DUEXIS® and FDA-approved uses.

ALKEM’S ANDA

29. On information and belief, Alkem submitted the Alkem ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market ibuprofen and famotidine tablets, 800 mg/26.6 mg. On information and belief, the Alkem ANDA seeks approval to market the Alkem Product for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials was defined as gastric and/or duodenal ulcer, in patients who are taking ibuprofen for those indications.

30. On information and belief, the Alkem ANDA refers to and relies upon the DUEXIS® NDA and contains data that, according to Alkem, demonstrate the bioequivalence of the Alkem Product and DUEXIS®.

31. Plaintiffs received from Alkem a letter, dated May 29, 2018 (the “Alkem Notification”), stating that Alkem had included a certification in the Alkem ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, the ’033, ’451, ’127, ’202, ’910 and ’228

patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the Alkem Product ("the Paragraph IV Certification").

32. The Alkem Notification states that the Alkem ANDA seeks approval to engage in the commercial manufacture, use or sale of ibuprofen and famotidine tablets, 800 mg/26.6 mg before the expiration of the '033, '451, '127, '202, '910 and '228 patents.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,067,033

33. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-32 of this Complaint.

34. The '033 patent issued on November 29, 2011, and will expire no earlier than July 18, 2026.

35. By submitting and seeking approval of the Alkem ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Alkem Product, prior to date on which the '033 patent expires, Defendant has infringed the '033 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

36. Defendant's commercial manufacture, use, offer to sell, or sale of the Alkem Product within the United States, or importation of the Alkem Product into the United States, during the term of the '033 patent, also would infringe the '033 patent under 35 U.S.C. § 271(a), (b) and/or (c).

37. Upon approval of the Alkem ANDA, and commercialization of the Alkem Product, Defendant will actively induce and/or contribute to infringement of the '033 patent.

38. Upon information and belief, Defendant had actual and constructive notice of the '033 patent as of its issue date, and Defendant's infringement of the '033 patent is willful.

39. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Alkem's ANDA be a date that is not earlier than the expiration of the '033 patent, or any later expiration of any exclusivity or extension of the '033 patent to which Plaintiffs or the patent may become entitled.

40. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the '033 patent.

41. Plaintiffs have no adequate remedy at law.

42. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 8,067,451

43. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-42 of this Complaint.

44. The '451 patent issued on November 29, 2011, and will expire no earlier than July 18, 2026.

45. By submitting and seeking approval of the Alkem ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Alkem Product, prior to date on which the '451 patent expires, Defendant has infringed the '451 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

46. Defendant's commercial manufacture, use, offer to sell, or sale of the Alkem Product within the United States, or importation of the Alkem Product into the United States, during the term of the '451 patent, also would infringe the '451 patent under 35 U.S.C. § 271(a), (b) and/or (c).

47. Upon approval of the Alkem ANDA, and commercialization of the Alkem Product, Defendant will actively induce and/or contribute to infringement of the ’451 patent.

48. Upon information and belief, Defendant had actual and constructive notice of the ’451 patent as of its issue date, and Defendant’s infringement of the ’451 patent is willful.

49. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Alkem’s ANDA be a date that is not earlier than the expiration of the ’451 patent, or any later expiration of any exclusivity or extension of the ’451 patent to which Plaintiffs or the patent may become entitled.

50. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the ’451 patent.

51. Plaintiffs have no adequate remedy at law.

52. This case is exceptional, and Plaintiffs are entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 8,309,127

53. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-52 of this Complaint.

54. The ’127 patent issued on November 13, 2012, and will expire no earlier than July 18, 2026.

55. By submitting and seeking approval of the Alkem ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale of importation of the Alkem Product, prior to date on which the ’127 patent expires, Defendant has infringed the ’127 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

56. Defendant's commercial manufacture, use, offer to sell, or sale of the Alkem Product within the United States, or importation of the Alkem Product into the United States, during the term of the '127 patent, also would infringe the '127 patent under 35 U.S.C. § 271(a), (b) and/or (c).

57. Upon approval of the Alkem ANDA, and commercialization of the Alkem Product, Defendant will actively induce and/or contribute to infringement of the '127 patent.

58. Upon information and belief, Defendant had actual and constructive notice of the '127 patent as of its issue date, and Defendant's infringement of the '127 patent is willful.

59. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Alkem's ANDA be a date that is not earlier than the expiration of the '127 patent, or any later expiration of any exclusivity or extension of the '127 patent to which Plaintiffs or the patent may become entitled.

60. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the '127 patent.

61. Plaintiffs have no adequate remedy at law.

62. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT IV FOR INFRINGEMENT OF U.S. PATENT NO. 8,318,202

63. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-62 of this Complaint.

64. The '202 patent issued on November 27, 2012, and will expire no earlier than July 18, 2026.

65. By submitting and seeking approval of the Alkem ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale of importation of the Alkem Product, prior to date on which the ’202 patent expires, Defendant has infringed the ’202 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

66. Defendant’s commercial manufacture, use, offer to sell, or sale of the Alkem Product within the United States, or importation of the Alkem Product into the United States, during the term of the ’202 patent, also would infringe the ’202 patent under 35 U.S.C. § 271(a), (b) and/or (c).

67. Upon approval of the Alkem ANDA, and commercialization of the Alkem Product, Defendant will actively induce and/or contribute to infringement of the ’202 patent.

68. Upon information and belief, Defendant had actual and constructive notice of the ’202 patent as of its issue date, and Defendant’s infringement of the ’202 patent is willful.

69. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Alkem’s ANDA be a date that is not earlier than the expiration of the ’202 patent, or any later expiration of any exclusivity or extension of the ’202 patent to which Plaintiffs or the patent may become entitled.

70. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the ’202 patent.

71. Plaintiffs have no adequate remedy at law.

72. This case is exceptional, and Plaintiffs are entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT V FOR INFRINGEMENT OF U.S. PATENT NO. 8,449,910

73. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-72 of this Complaint.

74. The '910 patent issued on May 28, 2013, and will expire no earlier than July 18, 2026.

75. By submitting and seeking approval of the Alkem ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Alkem Product, prior to the date on which the '910 patent expires, Defendant has infringed the '910 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

76. Defendant's commercial manufacture, use, offer to sell, or sale of the Alkem Product within the United States, or importation of the Alkem Product into the United States, during the term of the '910 patent, also would infringe the '910 patent under 35 U.S.C. § 271(a), (b) and/or (c).

77. Upon approval of the Alkem ANDA, and commercialization of the Alkem Product, Defendant will actively induce and/or contribute to infringement of the '910 patent.

78. Upon information and belief, Defendant had actual and constructive notice of the '910 patent as of its issue date, and Defendant's infringement of the '910 patent is willful.

79. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Alkem's ANDA be a date that is not earlier than the expiration of the '910 patent, or any later expiration of any exclusivity or extension of the '910 patent to which Plaintiffs or the patent may become entitled.

80. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the '910 patent.

81. Plaintiffs have no adequate remedy at law.

82. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VI FOR INFRINGEMENT OF U.S. PATENT NO. 8,501,228

83. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-82 of this Complaint.

84. The '228 patent issued on August 6, 2013, and will expire no earlier than July 18, 2026.

85. By submitting and seeking approval of the Alkem ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Alkem Product, prior to the date on which the '228 patent expires, Defendant has infringed the '228 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

86. Defendant's commercial manufacture, use, offer to sell, or sale of the Alkem Product within the United States, or importation of the Alkem Product into the United States, during the term of the '228 patent, also would infringe the '228 patent under 35 U.S.C. § 271(a), (b) and/or (c).

87. Upon approval of the Alkem ANDA, and commercialization of the Alkem Product, Defendant will actively induce and/or contribute to infringement of the '228 patent.

88. Upon information and belief, Defendant had actual and constructive notice of the '228 patent as of its issue date, and Defendant's infringement of the '228 patent is willful.

89. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Alkem's ANDA be a date that is not

earlier than the expiration of the ’228 patent, or any later expiration of any exclusivity or extension of the ’228 patent to which Plaintiffs or the patent may become entitled.

90. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the ’228 patent.

91. Plaintiffs have no adequate remedy at law.

92. This case is exceptional, and Plaintiffs are entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Defendants, and respectfully request the following relief:

A. A judgment declaring that Defendant has infringed one or more claims of U.S. Patent No. 8,067,033;

B. A judgment declaring the Defendant has infringed one or more claims of U.S. Patent No. 8,067,451;

C. A judgment declaring the Defendant has infringed one or more claims of U.S. Patent No. 8,309,127;

D. A judgment declaring the Defendant has infringed one or more claims of U.S. Patent No. 8,318,202;

E. A judgment declaring the Defendant has infringed one or more claims of U.S. Patent No. 8,449,910;

F. A judgment declaring the Defendant has infringed one or more claims of U.S. Patent No. 8,501,228;

G. If Defendant commercially manufactures, uses, offers to sell, or sells the Alkem Product within the United States, or imports the Alkem Product into the United States, prior to the expiration of the ’033 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

H. If Defendant commercially manufactures, uses, offers to sell, or sells the Alkem Product within the United States, or imports the Alkem Product into the United States, prior to the expiration of the ’451 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

I. If Defendant commercially manufactures, uses, offers to sell, or sells the Alkem Product within the United States, or imports the Alkem Product into the United States, prior to the expiration of the ’127 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

J. If Defendant commercially manufactures, uses, offers to sell, or sells the Alkem Product within the United States, or imports the Alkem Product into the United States, prior to the expiration of the ’202 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

K. If Defendant commercially manufactures, uses, offers to sell, or sells the Alkem Product within the United States, or imports the Alkem Product into the United States, prior to the expiration of the ’910 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

L. If Defendant commercially manufactures, uses, offers to sell, or sells the Alkem Product within the United States, or imports the Alkem Product into the United

States, prior to the expiration of the ’228 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

M. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Alkem ANDA shall be a date not earlier than the expiration date of the ’033 patent, inclusive of any extensions;

N. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Alkem ANDA shall be a date not earlier than the expiration date of the ’451 patent, inclusive of any extensions;

O. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Alkem ANDA shall be a date not earlier than the expiration date of the ’127 patent, inclusive of any extensions;

P. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Alkem ANDA shall be a date not earlier than the expiration date of the ’202 patent, inclusive of any extensions;

Q. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Alkem ANDA shall be a date not earlier than the expiration date of the ’910 patent, inclusive of any extensions;

R. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Alkem ANDA shall be a date not earlier than the expiration date of the ’228 patent, inclusive of any extensions;

S. Attorneys’ fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

T. Costs and expenses in this action; and

U. Such other and further relief as the Court deems just and proper.

Date: July 9, 2018

BARNES & THORNBURG LLP

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